

**LEGISLATIVE SERVICES AGENCY
OFFICE OF FISCAL AND MANAGEMENT ANALYSIS**

200 W. Washington, Suite 301
Indianapolis, IN 46204
(317) 233-0696
<http://www.in.gov/legislative>

FISCAL IMPACT STATEMENT

LS 6342

BILL NUMBER: SB 323

NOTE PREPARED: Feb 5, 2015

BILL AMENDED: Feb 5, 2015

SUBJECT: Waste Blood Specimen Requirements.

FIRST AUTHOR: Sen. Head

FIRST SPONSOR:

BILL STATUS: 2nd Reading - 1st House

FUNDS AFFECTED: **GENERAL**
 X DEDICATED
 FEDERAL

IMPACT: State

Summary of Legislation: (Amended) This bill adds retention and destruction requirements to the Indiana State Department of Health's (ISDH) epidemiological survey and research system for waste blood specimens. The bill specifies consent required under certain circumstances concerning waste blood specimens. The bill also allows a parent to request that the waste blood specimen of a newborn be destroyed not later than six months after collection. It specifies when identifiable information of waste blood specimens can be released, and sets forth requirements. The bill requires a fee to be assessed for certain people applying to use samples of the waste blood specimens.

Effective Date: July 1, 2015.

Explanation of State Expenditures: (Revised) The bill would require the ISDH to develop a form specifying that a parent wishes the waste blood specimen to be destroyed. This requirement should be accomplished within the current level of resources available to the ISDH.

Waste blood specimens are the dried blood spots remaining after the laboratory testing required for the newborn screening program. The bill would allow the Newborn Screening Program the option of storing waste blood specimens collected after July 1, 2015, for a period of up to 18 years. The current retention schedule for waste blood specimens is 3 years. Approximately 50% of parents currently elect to make their child's dried blood spot specimens available for medical research purposes. The program currently has the freezer capacity to store these samples for a period of 3 years. Should the retention period be extended past 3 years, additional storage capacity would be necessary. The ISDH has indicated that a walk-in freezer would work best for storage should the decision be made to extend the retention schedule for the specimens. The ISDH reported that a walk-in freezer would cost about \$100,000, plus an additional \$50,000 in rent would

be necessary if the retention schedule were extended.

Additional Information: Since June 2013, ISDH has been storing waste blood specimens in freezers as recommended by the Health Resources and Services Administration in order to prevent degradation of the samples. If a parent chooses to have a sample stored and to be made available for research, the current ISDH policy is to maintain the samples for a period of 3 years. Specimens that are not requested to be stored, are maintained for a period of 6 months for newborn screening follow-up purposes and then destroyed.

Explanation of State Revenues: The bill allows for the establishment of a fee to be assessed to a person applying for the use of waste blood specimen research purposes. The bill specifies that this fee is separate from and not to be included in the newborn screening fee. The amount of the fee will be determined by the level of effort required to collect the necessary samples requested. The bill does not designate where the proceeds of the fee should be deposited. Any additional revenue will likely be minor. The fee is intended to cover the cost of pulling samples from storage.

Explanation of Local Expenditures:

Explanation of Local Revenues:

State Agencies Affected: Indiana State Department of Health.

Local Agencies Affected:

Information Sources: “Briefing Paper; Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening”, Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children, Health Resources and Services Administration at:

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/briefingdriedblood.pdf> ; and Indiana State Department of Health.

Fiscal Analyst: Kathy Norris, 317-234-1360.